LOGISTICALLY *speaking*

Naval Medical Logistics Command, Fort Detrick, MD. **Spring Issue**

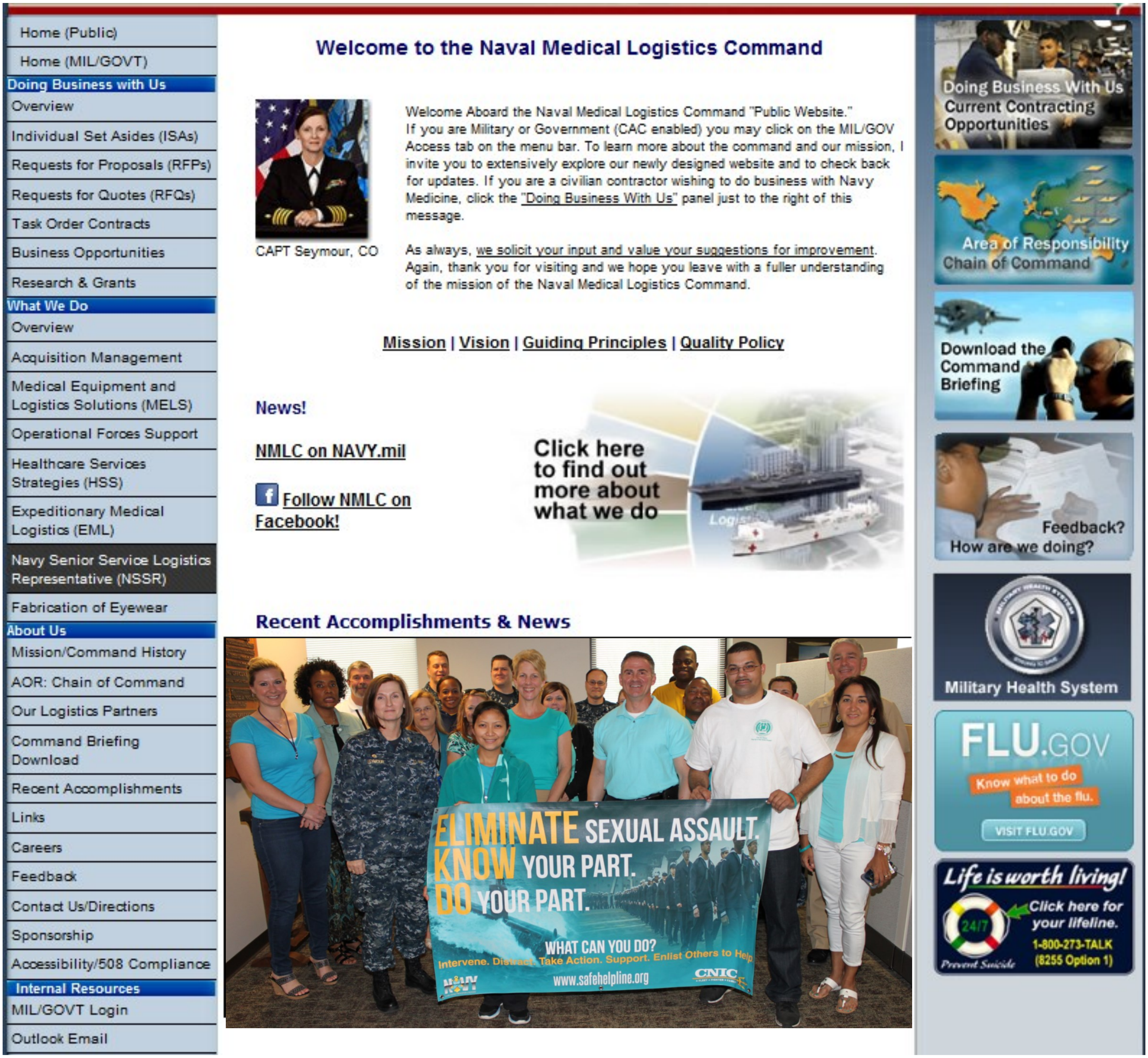
USS Theodore Roosevelt Battle Group

The USS Theodore Roosevelt (CVN 71) leads a flotilla of warships. (U.S. Navy photo.)

In fiscal year 2014, Naval Medical Logistics Command purchased medical equipment and materiel totaling $10.9M in support of U.S. Fleet Forces Command and U.S. Pacific Fleet ships. Approximately 70% of these requirements were procured using e-commerce purchasing processes through Defense Logistics Agency Troop Support contracts that provided materiel to the fleet faster and with reduced costs than using traditional contracting processes. In addition, Naval Medical Logistics Command processed 10,541 Authorized Medical Allowance List (AMAL) and Authorized Dental Allowance List (ADAL) maintenance actions that maximized shipboard use of joint clinically derived standardized products and enhanced supply chain responsiveness.

Naval Medical Logistics Command Website

http://www.med.navy.mil/sites/nmlc/Pages/default.aspx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Welcome to the Naval Medical Logistics Command

CAPT Seymour, CO

Welcome Aboard the Naval Medical Logistics Command "Public Website." If you are Military or Government (CAC enabled) you may click on the MIL/GOV Access tab on the menu bar. To learn more about the command and our mission, I invite you to extensively explore our newly designed website and to check back for updates. If you are a civilian contractor wishing to do business with Navy Medicine, click the "Doing Business With Us" panel just to the right of this message.

As always, we solicit your input and value your suggestions for improvement. Again, thank you for visiting and we hope you leave with a fuller understanding of the mission of the Naval Medical Logistics Command.

Your Resource to All Things Naval Medical Logistics Command

Naval Medical Logistics Command's mission: ***We deliver patient-centered logistics solutions for military medicine***. Naval Medical Logistics Command's vision: ***To become DoD's premier medical logistics support activity***. You can find all the timely information you need through the Naval Medical Logistics Command (NMLC) website.

On The Cover—Carrier Strike Group 12 is one of four U.S. Navy carrier strike groups currently assigned to the United States Fleet Forces Command. Carrier strike groups gain and maintain sea control as well as project naval airpower ashore. The aircraft carrier USS Theodore Roosevelt (CVN-71) is the strike group's current flagship. Other units currently assigned to Carrier Strike Group 12 include Carrier Air Wing One embarked on board the USS Theodore Roosevelt; the Ticonderoga-class cruisers Vicksburg and Normandy; and Destroyer Squadron 2.

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Not Easy, but Not Impossible

From the Commanding Officer

Capt. Mary S. Seymour, NMLC CO

In this issue of Logistically Speaking, the Command Master Chief discusses the different power bases effective leaders use on a day-to-day basis. In his description, he identifies the influence each one yields, the impact each one has, and the fact that a leadership position is not required to have some form of power.

In this fiscally conservative state the Department finds itself, our Resources Directorate contributed an article that highlights the importance of audit readiness as it pertains to Navy Medicine's financial operations. It focuses on support agreements and Support Agreement Managers. I am certain you will find a great deal of value in its content.

The Clinical Engineering Division highlights the Naval Laboratory Equipment Review Board and the Naval Diagnostic Imaging and Radiotherapy Board, their significance and some of the inner workings of the boards. A bit technical in nature, this article is packed with timely information. In addition, our Biomedical Operations Division explains Hazards, Alerts and Recall notifications.

NMLC's Small Business Advisor does it again by contributing a very timely article that focuses on the significance of Women-Owned Small Business (WOSB) sole source contracts and how they are moving closer to reality. Although WOSB firms are their own socio-economic category among small businesses, they only received this recognition recently. Read how they continue to mature in industry's eyes.

This issue features a section, Lead Contracting Executive News and Notes, that we intend to bring to you more frequently from our Acquisition Management and Analytics Directorate. In this section, you will find a variety of information that spans our various Contracts divisions. If you have anything to do with contracts, you may not wish to look over this area.

We close out this issue of Logistically Speaking with an article on Medical Technology Cybersecurity. One of NMLC's information specialists wrote this article, the first of a two-part series, to identify how to successfully address medical device cybersecurity.

We continue to seek your feedback and suggestions on articles you would like to see or contribute to a future issue of Logistically Speaking. Feel free to communicate directly with our public affairs office and we will continue to be responsive to your feedback.

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Articles should be submitted to:
The Public Affairs Officer

From the Command Master Chief

I recently had a discussion with our Petty Officer's Mess during a mentoring session regarding power and leadership. What was interesting during our session is that they were not aware of the different power bases that effective leaders use daily. Understanding where power comes from can influence the way we work, act and behave in our workplace or daily life. Also, it helps us to recognize our own source of power and build our leadership skills.

There are five bases of power, studied by social psychologists John French and Bertram Raven in 1959. They are: Legitimate, Reward, Expert, Referent and Coercive. Legitimate power comes from the formal right to make demands and to expect people to follow orders and/or directions. An example of legitimate power is our Commanding Officer. Reward power comes from one's ability to honor and recognize accomplishments due to compliance. This is often expressed during the receipt of an award or recognition ceremonies. Expert power is based on a person's superior knowledge and skills in their job. We see this used a lot when we seek advice and/or assistance from our Subject Matter Experts who have demonstrated their expertise, knowledge and skills in areas that you are not familiar with. Referent power comes from being trusted and respected as a person. Charm, admiration and esteem are conveyed through behaviors in which a person likes and respects another. Coercive power comes from the belief that a person can punish another for failing to comply. Not a widely used base of power, coercive power is particularly used in situations of imminent danger or threat.

HMCM(FMF) David L. Hall, NMLC CMC

As mentioned to our Petty Officers, we don't have to be in a leadership role to have some form of power. We all demonstrate leadership traits daily in one or more forms of the power bases. Power is effective when used properly and, once developed, can transform leaders into influential and respected members of our organization.

Capt. Mary Seymour, Commanding Officer, Naval Medical Logistics Command, congratulates HM1 (SW) Keith Skelley and HM1 (SW/FMF) Joseph Watkins on receiving an 'outstanding' during the Summer Whites Personnel Inspection. Also pictured are Lt. Cmdr. Diana Garcia, who presented the command to the commanding officer, HMC (SW/AW) Howk, standing in as command master chief, and HM2(FMF) Eric Czech, who performed the duties as recorder.

Audit Readiness - An Important Part of Navy Medicine's Financial Operations

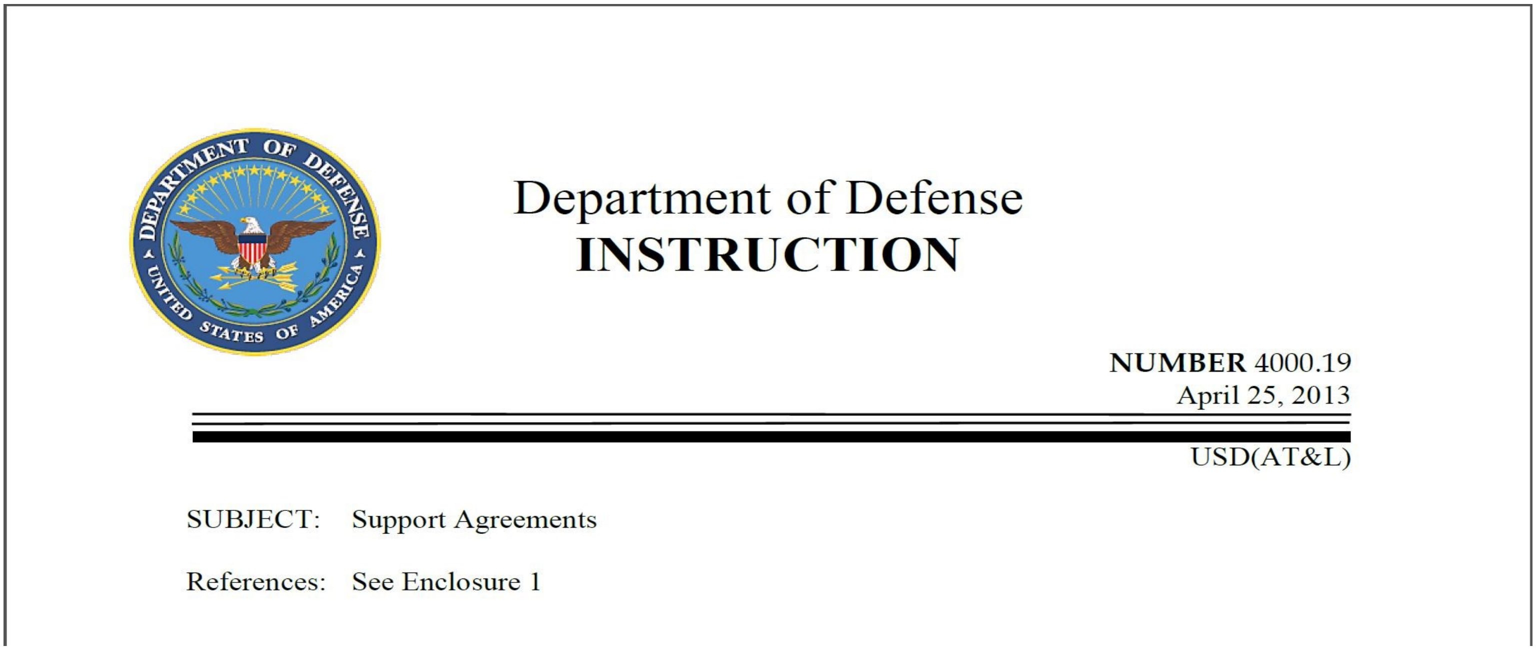
By Samanthia Henderson, NMLC Deputy Comptroller

Audit Readiness has become an important and integral part of the Navy Medicine's daily financial operations. As defined by the Office of Financial Operations (FMO), Audit Readiness is a state of being prepared at all times to demonstrate proper manual and automated processes and documentation (e.g., process controls, financial controls, Information Technology (IT) controls) that are executed in accordance with policy and appropriate accounting standards. One of the many key components supporting Audit Readiness includes the use of Support Agreements (SAs). To ensure proper use and conformance with policy, standard operating procedures have been established under the Navy's Financial Improvement Program.

Support Agreements may be defined as a contractual document between a supplying and receiving Activity which will document each activity's responsibility in regards to support requirements (provided and received). Each agreement will specify the kind and level of support to be provided by the supplying activity, applicable reimbursement arrangements, and any other matters affecting the execution of the agreement. Although the support agreement is not a contract per se, it is considered a binding agreement between two organizations which cannot be contractually bound by traditional contract vehicles.

"Establishing the use of a support agreement has been one of the most effective tools that we can use, particularly in situations when organizations are limited by the types of agreements in which they can go into," said Lt. Cmdr. Diana Garcia, NMLC's Comptroller. "But because SAs are so reliable, they have become the vehicle of choice for organizations that cannot otherwise be contractually bound."

Naval Medical Logistics Command currently has 17 SAs in effect. It has oversight, review and first endorsement responsibility of 20 SAs for its two subordinate commands, Navy Expeditionary Medical Support Command and Naval Ophthalmic Support and Training Activity. These support agreements cover various



Department of Defense
INSTRUCTION

NUMBER 4000.19
April 25, 2013

USD(AT&L)

SUBJECT: Support Agreements

References: See Enclosure 1

supporting services that include internet connectivity, utilities, facilities, materiel storage of pharmaceuticals, and training; and supporting both reimbursable and non-reimbursable documents. The SAs consist of intraservice, interservice, intragovernmental, Non-Federal, commercial and non-commercial agreements executed between various entities within the Navy and other agencies.

A key factor that promotes the success of a Command's Support Agreement Program is to appoint a Support Agreement Manager (SAM).

To be successful, the SAM must be familiar with the Navy Medicine Standard Operating Procedures (SOP), Support Agreements: Receiver Side, DODINST 4000.19, and BUMEDINST 7050.1B. The combination of these policies and guidance are excellent references to that should be used to create (and sustain) an auditable support agreement program. It is the SAM's responsibility to maintain a record of all support agreements and validate content of the agreement to ensure compliance with policy and track the status of each agreement.

Each activity's SAM conducts the first level review for new and renewal of expiring SAs. He/she validates all required supporting documentation is included in the SA package in accordance with the BUMED Support Agreement SOP ensuring the use of BUMED's Standard clauses. The SAM will also coordinate with the subject matter experts to conduct an annual review of each agreement to determine if the level of support provided by the SA is a valid requirement and consistent with the command's mission. Any change to the services provided, increase or decrease in funding or change in either parties responsibilities, must be documented by a modification. Upon completion of SA package, it is routed to the activity Legal Counsel Office for review and concurrence, enhancing the effectiveness and auditability of the command's Support Agreement Program. The Legal Office will identify any potential liabilities issues, ensure proper statutory authority, and validate the needs identified by the Receiver does not conflict with any laws or regulations.

The activity comptroller will review the type of goods and services provided and ensure funding amounts specified are necessary for the execution of the support agreement. The Commanding Officer or Officer-in-Charge reviews and validates the SA package to ensure the need and justification of goods and services and will sign a transmittal letter to be forwarded with the SA package. The SAM is responsible for forwarding the information to the Regional SAM. **LS**

Clinical Engineering Division

By Naval Medical Logistics Command's Clinical Engineering Division

Submission Deadlines for Centrally Funded Equipment Requests

7 September 2015 – Echelon IV Commands are to submit FY17 OP, DHP equipment request packages and list of equipment with unit/system cost of $250,000 and over to their respective Navy Medicine Region/ Client Executive command and Naval Medical Logistics Command (Medical Equipment & Logistics Solutions).

Naval Laboratory Equipment Review Board (NAVLERB). BUMEDINST 6700.44 BUMED-M4 25 Nov 2014

The NAVLERB, established in the first quarter of FY 2015, serves as an advisory board to the Chief, Bureau of Medicine and Surgery (BUMED) and evaluates new and emerging medical laboratory technologies. The board will also recommend short and long range planning, policy, governance, and acquisition strategies for laboratory equipment and related support equipment. Future NAVLERB meetings are currently scheduled for 11 August 2015 and 13 October 2015.

All individual or group medical laboratory equipment acquisitions with a unit/system cost of $3,000 and over should be reviewed by the NAVLERB to ensure standardization and quality are in line with strategic objectives. Such equipment shall include all cost per test/reportable contracts, equipment leases, inter-facility test transfers, reference laboratory contracts, and medical laboratory equipment maintenance costs for Navy Medicine.

To manage the number of requests and to address issues of policy, the NAVLERB will convene at least once a quarter. Ad hoc meetings or electronic voting between quarterly meetings may also be coordinated as the Chairperson of the NAVLERB sees fit. Equipment requests must be received at Naval Medical Logistics Command at least 30 days prior to the meeting date to allow adequate time for review and processing.

Naval Diagnostic Imaging & Radiotherapy Board (NAVDIRB) BUMEDINST 5420.19A BUMED-M4 24 Jun 2014

The NAVDIRB serves to evaluate new and emerging medical and dental imaging and radiotherapy technologies. The board will recommend short and long range planning, policy, governance, and acquisition strategies for all diagnostic imaging, radiotherapy equipment modalities, and related support equipment, including Military Construction (MILCON) projects.

All diagnostic imaging and radiotherapy equipment requests will require review by the NAVDIRB to validate the requirement and ensure standardization and quality are in line with strategic objectives. Such modalities will include, but not limited to, radiography, fluoroscopy, mammography, computed tomography, ultrasonography, interventional radiology, nuclear medicine, magnetic resonance imaging, magnetoencephalography, linear accelerator radiotherapy, brachytherapy, tomotherapy, and proton beam therapy.

Future NAVDIRB meetings are currently scheduled for 12 August 2015 and 9 December 2015. Equipment requests must be received at Naval Medical Logistics Command at least 45 days prior to the meeting date to allow adequate time for review and processing. **LS**

Hazards, Alerts and Recall Notifications

By Naval Medical Logistics Command's Biomedical Operations Division

In the interest of patient and operator safety, Naval Medical Logistic Command facilitates and monitors medical material Hazards, Alerts and Recall (HAR) notifications. This service provides support to all Medical Treatment Facilities (MTFs) and Navy and Marine Corps operating forces while maintaining compliance with standards of the Safe Medical Device Act of 1990.

In 2014, Navy Medicine had a total of 414 medical equipment related alerts which included messages from Medical Materiel Quality Control, FDA MedWatch, ECRI Alerts Tracker and Equipment Manufacturers. There were 197 HAR messages that directly affected BUMED, including 12 Class 1 recalls. Class 1 recalls indicate a reasonable probability that the use of or exposure to the device will cause serious adverse health consequences or death.

Each command must have a standard operating procedure and a designated HAR Coordinator to facilitate, monitor and document in Defense Medical Logistics Standard Support (DMLSS) all administrative and maintenance actions performed in response to each recall or alert.

It is imperative that equipment records be documented with accurate valuation data as this is critical in determining affected equipment within the inventory. In DMLSS, the Nameplate Model, Serial Number, and Manufacturer Information are mandatory fields. The Common Model is not mandatory. However, alerts and recalls typically refer to the Common Model as search criteria. Therefore, it is highly recommended this information be included and accurately documented.

Please refer to the Hazards, Alerts and Recall Process (Enclosure 6 in the FY-15 Logistics Guidance) for additional information about Hazards, Alerts and Recall notifications. This document may be retrieved by clicking on the following link: https://gov_only.nmlc.med.navy.mil/guidance/enclosures/Alerts%20and%20Recalls%20Process.pdf. **LS**

SMALL BUSINESS PROGRAMS

WELCOME TO BIZ BUZZ !

Biz Buzz is where you will find what's happening with NMLC's Small Business Program Office, as well as general small business information and news you can use.

What's the BUZZ?

By Mimi McReal, Naval Medical Logistics Command's Small Business Advisor

WOMEN OWNED
SMALL BUSINESS
FEDERAL CONTRACTING PROGRAM
★ ★ ★ ★ ★ ★ ★ ★ ★ ★ ★

The Buzz is - Women-Owned Small Business sole source contracts….moving closer to reality! The 2015 National Defense Authorization Act (NDAA), Section 825, contains a provision authorizing federal agencies to award sole source contracts to women-owned small businesses that are eligible for the Woman-Owned Small Business (WOSB) Federal Contract Program. This provision gives women improved access to the federal contracting marketplace, as is the case with other disadvantaged groups. The Small Business Administration (SBA) announced the proposed rule on 1 May 2015 and will be accepting comments until 30 June 2015. The SBA will review the comments and issue a final rule, after which the ability to sole source federal contracts to WOSB will follow.

Although WOSB firms are their own socio-economic category among small businesses, it was only recently that they received this recognition. While Congress established the WOSB Federal Contract program in legislation in 2000, also referred to as, the "Equity in Contracting for Women Act of 2000", it was not implemented until several years later, in 2011. Under the 2013 NDAA, a Bill entitled, "Fairness in Women-Owned Small Business Contracting Act of 2012" was introduced. Providing economic opportunity to women-owned small businesses has been a top priority for the SBA and President Obama's administration.

Fast-forward to July, 2014, when the SBA Administrator, Ms. Maria Contreras-Sweet, testified before the U.S. Senate Committee on Small Business and Entrepreneurship that federal agencies "…needed a tool to level the playing field for women-owned businesses…" because WOSB firms were still lagging far behind attainment of the statutory goal of 5% of federal contract awards. Many of the committee members were also in strong support and the SBA worked with Congress and key small business stakeholders to include this provision. Implementing sole source contract awards is critical to promoting WOSB firms and will open doors for them.

Once finalized, sole source contract awards to WOSBs will still need to follow similar criteria required of sole source contract awards to other socioeconomic small businesses, such as awards to HubZone, 8(a), and Service-Disabled Veteran-Owned (SDVOSB) firms, as outlined in FAR Part 19. WOSB sole source contract awards must demonstrate that: (1) the contracting officer does not have a reasonable expectation that two or more economically-disadvantaged, women-owned small business (EDWOSB) or WOSBs will submit offers; (2) the anticipated award price (including options) will not exceed $6.5 million for manufacturing contracts and $4 million for other contracts; (3) the EDWOSB/WOSB is responsible; and (4) in the estimation of the contracting officer, the award can be made at a fair and reasonable price.

Over the last decade and a half, WOSBs have struggled, receiving approximately 2% to 3% of federal contracting dollars awarded to small businesses, well below the 5% statutory goal. Going forward with the provision to sole source contracts to WOSB firms should bolster the success of one of the fastest growing groups in the economy, while moving toward meeting, or perhaps exceeding, the 5% goal.

Information for this article was obtained in part from the following sources: Small Business Administration (SBA) (www.sba.gov); the Federal Register (www.federalregister.gov); and www.whitehouse.gov . For any questions on this article or if you have any suggestions for future articles, please contact Ms. McReal at Marianna.mcreal.civ@mail.mil. **LS**

Lead Contract Executive News and Notes

By Gilbert Hovermale, BUMED Lead Contracting Executive & NMLC Director, Acquisition Management and Analytics

This issue's column: Using Fair Opportunity For Consideration for DLA Electronic Catalog (ECAT) Orders

Navy Bureau of Medicine and Surgery (BUMED) ordering officers are required to provide ECAT vendors fair opportunity for consideration when placing orders between $3,000 and $150,000. Fair opportunity simply means that the ordering officer must consider at least 3 vendors before selecting the successful vendor and placing the order. The ordering officer has broad discretion regarding what factors to consider when comparing the three vendors. The ordering officer must always consider price as one of the factors. Other factors may include the bandwidth, throughput or sensitivity of the equipment, special features of the equipment or its ease of use, the vendor's maintenance and customer support program, and an activity's history with the particular model or manufacturer.

The ordering officer need not select the lowest priced vendor. He or she can make a best value source selection decision to a higher priced vendor. To make a best value decision, start with the lowest priced vendor and climb up the price ladder. At each rung of the ladder (each successively higher priced vendor) ask yourself the question, "Considering the comparative factors I've chosen (features, supportability, experience, etc.), am I getting commensurate value for the extra price I'm being asked to pay?" If you decide you are not getting commensurate value, stick with the lower priced vendor. If a higher price does come with better value, then you have the basis for a good best value decision.

The ordering officer must document which vendors he or she considered (manufacturer, model, and any associated consumables or peripheral items), which factors were used as the basis of comparison (price, throughput, features, etc.), and which vendor was selected and why. A simple Excel spreadsheet or Word table works great as a comparison tool. The award decision itself can usually be documented in just a sentence or two: "I selected vendor ABC, Model 123, because its combination of faster throughput and better training and warranty is worth the additional $200 over vendor XYZ's model. Vendor DEF was significantly higher in price and did not offer commensurate value for the price." The ordering officer can create a file for this documentation or use the Notes feature in the Defense Medical Logistics Standard Support (DMLSS) system. Be careful if you use DMLSS because DMLSS Notes won't hold a table format. You may need to play around with the text in your note until you are able to show the comparison clearly.

Q-Tip: Think carefully before throwing a mash up of unrelated items into an ECAT order totaling more than $3,000. It will be very difficult to do "apples to apples" comparisons for fair opportunity.

PPMAP HIGHLIGHTS

By Aurita Rose and Kelly Sherman, Supervisory Contract Specialists, Acquisition Management and Analytics

NMLC began conducting Procurement Performance Management Assessment Program (PPMAP) reviews for BUMED purchasing activities in FY15. As of 30 April, 20 reviews have been completed and four desk reviews and two onsite reviews are in the process of being scheduled.

Some common problems found:

Review of vendors in System for Award Management (SAM). In accordance with (IAW) FAR 9.405-(d)(4), SAM must be checked at receipt of proposals and immediately prior to Contracting Officer release of award.

Failure to document screening from mandatory Government sources of supply. NAVSUPINST 4200.85D (Chapter 4) discusses the requirement for screening requirements for their availability form mandatory Government sources of supply. Documentation of this screening must be included in the file.

Missing DD Form 2579s. DFARS 219.201 requires the Small Business Specialist to review each requirement exceeding $10,000, including orders against FSS/GSA contracts. The review must be documented using the DD Form 2579. DD 2579s were missing when required.

Failure to document the best value decision in the ordering file for actions over $3000. Multiple award contracts are established by the General Services Administration (GSA) to provide a choice of available options to the customer. Both price and technical quality must be considered in the best value decision. Orders should be documented to show that the best value determination was based on low price or other factors in accordance with FAR 8.405 and DFARS 208.404. Best value refers to considerations such as price, delivery, warranty, or technical factors that cause the item selected to represent the best value to the Government among the potential awardees.

Best practices noted with 'Shout outs' to the following activities:

At Naval Hospital Camp Lejeune, due to a recent split of the Purchase Card and Contracting teams, it was noticed that recent contract/order files are policy compliant. Separating contracting and purchase card functions allows contracting personnel to report directly to a Supervisory Contract Specialist. This facilitates consistent guidance, monitoring, and training on ever changing contract policy and process requirements.

We anticipate uncovering more best practices in the future!

We look forward to completing our 3rd and 4th quarter reviews. For a complete listing, the PPMAP Tentative Schedule is contained on NMLC's LCE website at https://gov_only.nmlc.med.navy.mil/lce/ under Authority Management & PPMAP.

Q-Tip: A helpful tip for a complete desk review is to provide the entire contents of your files with the initial submission. This eliminates the need to request additional documentation during the review.

Unauthorized Commitments Reporter

By Sharon Leathery, Contract Specialist, Acquisition Management and Analytics

NMLC began 3rd QTR FY15 with 49 UACs pending. During the quarter, nine new UACs were received and nine were ratified. The quarter ended with 49 UACs pending.

Causes for new Unauthorized Commitments:

1. Orders exceeded totals authorized on contracts.
2. Orders placed against expired contracts.
3. Staff lacked purchasing warrant authority.
4. Duplicate orders placed and received.
5. Services rejected for payment by Tricare.

Changes in Policy or Process: Keep in mind that guidance provided under BUMED ltr 7000 Ser M46/15UM40006 (19 March 2015), now requires complete UAC packages to be submitted through the appropriate Regional first Flag Officer within 60 days of notification to NMLC.

Q-Tip: Establishing price reasonableness is a necessity for ratification, so please include quotes and/or other pricing documentation with your UAC submission in order to expedite analysis and processing,

Contract Administration Division

By Tameka Davis, Supervisory Contracting Officer, Acquisition Management and Analytics

Documentation – A Contract Administration Best Practice

Often times, Administering Contracting Officers are asked to fix a problem, find an immediate solution to an ongoing problem, possibly find a new healthcare worker or replace an old one. With Contract Administration, there's always something that needs the Contracting Officer's attention. In any given situation, the Contracting Officer will need information and documentation in order to make a recommendation, decision, or change. He or she will need the full picture, the whole story, the good and the bad. To do this, it's important that throughout the process, whether the situation has roots going back years, or just arose a few hours ago, the personnel involved document the who, what, when, why and how of the given issue or situation. Noting these things at the time of the occurrence can be extremely useful when they need to be referred to at a later time. It could be an email, a note about a phone call, standard forms, or formal notes. Those are just examples and there really is no limit. It helps the Contracting Officer make the best decision on the solution and find a way forward. It helps the Command receive the best service and allows a solution to be implemented. Absence of documentation could delay a solution.

Q-Tip: Document! Document! Document! Regardless of how large or small and event may seem, personnel involved should always document the occurrence. Memories can fade, people can move on and contracts can come and go.

It's imperative that contemporaneous documentation stays. **LS**

Medical Technology Cybersecurity—Not Easy, but Not Impossible

By Walter J. Sandman

This is the first of a two part article.

Attempting to address cybersecurity of medical devices is undoubtedly a daunting task. Without exception, the medical industry has continued to evolve at an unprecedented pace in recent years. It is almost a daily occurrence to read in the news about a new scientific breakthrough or the introduction of new technologies that can improve the quality of healthcare. As a result of increasing demands imposed on accuracy and rapid availability of medical information, the reliance upon Information Technology (IT) components in medical devices is ever increasing with no end in sight. Furthermore, it is quite common these days to speak of medical technology and, more specifically, medical devices requiring some form of integration with other sources of information, most of which interface with other systems. If the end goal is to attain a complete medical record that can effectively paint the big picture, it would seem that integrating medical devices is the only way to see this goal become reality.

If we consider the fact that the medical manufacturing community and the medical industry, in particular, is constantly striving to achieve higher efficiency, it would seem that not much consideration has been given to protecting the information these devices process and that the focus has always been on accuracy and efficiency, not information security.

The process by which risk is measured applies to almost everything these days. The same model is used to assess systems ranging from complex architectures spanning entire enterprises to the most simple of end-point devices. The same holds true for every medical system and device in our environment regardless of level of complexity. The process is well defined; however, the same rules that traditional IT systems must abide by cannot easily be applied to medical devices. At first glance, it would seem logical to apply the latest and greatest software update on a given system. The advantages are obvious. Application code flaws are being discovered at an alarming rate and operating system and database developers are correcting these as soon as they are discovered in order to avoid exploitation by cybercriminals. It is effectively a race against time in which the end goal is to make sure that weaknesses in the code are rapidly corrected before they are discovered.

If a given vulnerability were to affect a desktop computer for example, taking immediate action to remediate it would not only be the responsible thing to do by protecting the affected computer, but to a larger extent decrease the overall risk for the entire network by preventing the use of the same desktop computer as a conduit aimed at deliberately compromising other systems that perhaps contain more valuable information.

Since the application of security updates appears to be a straight forward process, what is the risk should the process fail?

In the case of the traditional general purpose desktop computer, a failed installation of a software update aside from a possibly unexpected reboot will require a call to the local IT Department, which may incur minimal downtime before the issue is corrected, or perhaps a loaner computer can be issued in the interim so as to minimize downtime.

What about a similar scenario, only this time affecting a medical device? The consequences may range from a brief disruption in healthcare services to far more serious cases in which patient safety is directly compromised, perhaps resulting in misdiagnosis or worse yet, possible loss of life as a result or a complete medical device malfunction during an invasive procedure. In this case, “normal” IT practices cannot be applied. For example, there are not typically any loaner medical devices to give the healthcare provider if it is disabled as a result of a failed update. Federal law states that if a patient is grievously harmed during the routine use of a medical device, the device manufacturer is held responsible. Conversely, if non-validated changes are made to the medical device, even a simple operating system update, after which a patient is harmed, the organization that altered the medical device is held responsible. The only individuals trained and authorized to repair or install validated updates, patches or other configuration changes are Biomedical Equipment Technicians (BMET’s).

Despite the nuances of medical technology, all systems utilizing IT components are required to adhere to DoD cybersecurity requirements. In light of this, and recognizing the risk that commercial-off-the-shelf (COTS) medical technologies present to our network, Naval Medical Logistics Command is actively working with medical device manufacturers to comply with DoD policies to the extent practicable.

Part two of this article will explain the steps that are being taken to achieve compliance with DoD cybersecurity policy. **LS**

LOGISTICALLY *speaking*

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